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Notice of Allowability	Application No.	Applicant(s)	
	10/719,555	ANTHONY NELSON ET AL.	
	Examiner	Art Unit	
	Frederick F. Krass	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment dated 1-14-05.
2. ☒ The allowed claim(s) is/are 32-37.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|---|
| <ol style="list-style-type: none"> 1. <input type="checkbox"/> Notice of References Cited (PTO-892) 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | <ol style="list-style-type: none"> 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>4-29-05</u>. 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance 9. <input type="checkbox"/> Other _____. |
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Examiner's Amendment

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Erika Singleton Wilson on 4-29-05.

The following changes have been made:

1) Claims 12, 23, 25, 27, 29 and 31 have been canceled without prejudice thereto.

2) The following new claims have been added in their place:

--- Claim 32. A dentrifice in the form of a toothpaste or tooth gel, comprising:

a) from about 0.01% to about 10% of a phenolic, by weight of said dentrifice, said phenolic comprising a combination of menthol, eucalyptol, methyl salicylate, and thymol;

b) from about 0.1% to about 60% of a soluble cyclodextrin, by weight of said dentrifice, said cyclodextrin being capable of solubilizing said phenolic and being selected from the group consisting of hydroxypropyl beta-cyclodextrin, hydroxyethyl beta-cyclodextrin, hydroxypropyl gamma-cyclodextrin, hydroxyethyl gamma-cyclodextrin, alpha-cyclodextrin and methyl beta-cyclodextrin, and mixtures thereof;

c) from about 0% to about 25% of ethanol, by weight of said dentrifice;

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d) from about 0.5 to about 4% of a nonionic and/or anionic surfactant, by weight of said dentrifice;

e) up to 60 percent of an orally acceptable dental abrasive, by weight of said dentrifice;
and

f) an orally acceptable carrier;

said dentrifice being stable and free of precipitants, flocculants or crystals after storage at about 5°C to about 25°C for at least about one week.

Claim 33. A dentrifice according to claim 32, comprising an orally acceptable fluoride source sufficient to provide from about 250 ppm to about 1500 ppm fluoride.

Claim 34. A dentrifice in the form of a toothpaste or tooth gel, comprising:

a) from about 0.01% to about 3% of a phenolic, by weight of said dentrifice, said phenolic comprising a combination of menthol, eucalyptol, methyl salicylate, and thymol;

b) from about 0.1% to about 30% of a soluble cyclodextrin, by weight of said dentrifice, said cyclodextrin being capable of solubilizing said phenolic and being selected from the group consisting of hydroxypropyl beta-cyclodextrin, hydroxyethyl beta-cyclodextrin, hydroxypropyl gamma-cyclodextrin, hydroxyethyl gamma-cyclodextrin, alpha-cyclodextrin and methyl beta-cyclodextrin, and mixtures thereof;

c) from about 0% to about 25% of ethanol, by weight of said dentrifice;

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d) from about 0.5 to about 4% of a nonionic and/or anionic surfactant, by weight of said dentrifice;

e) up to 40 percent of an orally acceptable dental abrasive, by weight of said dentrifice;

f) an orally acceptable fluoride ion source sufficient to provide from about 250 ppm to about 1500 ppm fluoride; and

g) an orally acceptable carrier;

said dentrifice being stable and free of precipitants, flocculants or crystals after storage at about 5°C to about 25°C for at least about one week.

Claim 35. A method for retarding development of plaque on a dental surface in the oral cavity of a mammal in need thereof, comprising administering to said dental surface of said mammal an effective amount of a dentrifice according to claim 32.

Claim 36. A method of treating gingivitis in a mammal in need thereof, comprising administering to said mammal an effective amount of a dentrifice according to claim 32.

Claim 37. A method of reducing the viable population of microorganisms in the oral cavity of a mammal in need thereof, comprising administering to said mammal an effective amount of a dentrifice according to claim 32.

Reasons for Allowance

The following is an examiner's statement of reasons for allowance:

Applicant has discovered that certain cyclodextrins can be used to solubilize certain specific mixtures of essential oils, thus providing clearer, more stable compositions, while reducing the amount of ethanol needed. Such formulation problems are well known in this art; see for example USP 5,891,422 at lines 39-46. Accordingly, it is clear that Applicant has unexpectedly solved a longstanding problem in the art.

It is noted that the instant inventor is named on a number of other patents which are generally similar to the instant application. No issues of obviousness-type double patenting are raised thereby, however, because the conflicting claims are drawn to patentably distinct variants of the instantly claimed compositions. See, e.g., USP 6,261,540 (claiming non-obvious, unexpectedly stable compositions containing peroxides, which are normally expected to be unstable in the presence of water and/or hydrogen functionality); see also USP 6,534,042 and 6,235,267 (claiming the non-obvious incorporation of citrus flavor taste masking antagonists, which unexpectedly reduce the unfavorable bitterness and "bite" normally associated with this particular mixture of essential oils).

Note also that the previous examiner repeatedly required species elections, and specifically stated in USSN 09/772,269, at paper no. 5, p. 3, ¶ 3 that "U.S. 5,945,088 is [drawn] to a patentably distinct oral rinse" (emphasis added). Thus, the prosecution histories of the parent cases (which are very obtuse and difficult to follow) establish that dentrifices (toothpastes/gels) and oral rinses (mouthwashes) have been restricted from one another as patentably distinct species. Accordingly, USP 5,945,087, likewise drawn to an oral rinse, is also viewed as reciting a patentably distinct variant of the instantly claimed compositions. (Note that applicant's representative concurs with this interpretation – see the attached Interview Summary Form).

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue

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fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick F. Krass whose telephone number is 571-272-0580. The examiner's schedule is as follows:

Monday: 10:30AM- 7PM;
Tuesday: 10:30AM - 7PM;
Wednesday: off;
Thursday: 10:30AM- 7PM; and
Friday: 10:30AM-7PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frederick Krass
Primary Examiner
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